II. Amendments to the claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Currently Amended) A solid, oral, controlled release pharmaceutical dosage form ~~which comprises an extrudate~~ comprising a pharmaceutically active ingredient having a solubility in water of greater than 1gm in 250ml water at 25°C, dispersed in a matrix wherein the dosage form provides, as tested by the Ph. Eur. Basket method at 100 rpm 900 ml aqueous buffer (pH 6.5) containing 0.05% w/w Polysorbate 80 at 37°C, an essentially zero order rate of release of the pharmaceutically active ingredient over a period of 8 hours, the amount of pharmaceutically active ingredient released over eight hours being in the range of 15% to 45%, and when tested in a group of at least five healthy humans the median tmax, based on blood sampling at half hourly intervals, is in the range of from about 2.5 to about 6 hours, and the ratio of mean Cmax to the mean plasma level at 24 hours is in the range of about 1.5 to about 3.5~~, wherein said extrudate is directly incorporated into a capsule or tablet~~.

2. (Original) A pharmaceutical dosage form according to claim 1, wherein the median tmax is in a range from 2.5 to 3.5 hours.

3. (Previously presented) A pharmaceutical dosage form according to claim 1, which has a W_{50} in the range from about 15 to about 35 hours when tested *in vivo* as set forth in claim 1.

4. (Previously presented) A pharmaceutical dosage form according to claim 1, wherein the matrix comprises a mixture of an hydrophobic fusible material having a melting point of greater than 40°C and a hydrophilic, organic, polymeric fusible wicking agent.

5. (Previously presented) A pharmaceutical dosage form according to claim 4, wherein the weight ratio of hydrophobic fusible material to hydrophilic , organic polymeric wicking agent in said mixture is in the range from about 8:1 to about 16:1

6. (Previously presented) A pharmaceutical dosage form according to claim 1, in which the pharmaceutically active ingredient is morphine, a pharmaceutically acceptable salt thereof or mixtures thereof.

7. (Original) A pharmaceutical dosage form according to claim 5, which is suitable for once a day dosing.

8. (Previously presented) A pharmaceutical dosage form according to claim 1, in the form of a tablet or a capsule containing multiparticulates.

9-10 (Canceled)

11. (Currently amended) A solid, oral controlled release pharmaceutical dosage form which comprises a pharmaceutically active ingredient having a solubility in water of greater than 1gm in 250ml water at 25°C dispersed in a matrix, the dosage form being obtainable by a process comprising:

(a) mechanically working in a high shear mixer a mixture of hydrophobic, fusible binder and ~~a minor amount of~~ an organic, fusible, polymeric material which in the finished dosage form is capable of functioning as a wicking agent at a speed and temperature at which the binder melts or softens and the mixture forms agglomerates;

(b) extruding the agglomerates whereby the extrudate is obtained as extruded pieces or an elongate extrudate is formed into pieces;

(c) continuing mechanically working the pieces in a high shear mixer; and

(d) continuing mechanically working with additional binder material at a temperature and speed at which the additional binder melts or softens.

12. (Previously presented) A pharmaceutical dosage form according to claim 1, which has a W_{50} in the range from about 20 to about 30 hours when tested *in vivo* as set forth in claim 1.

13. (Previously presented) A pharmaceutical dosage form according to claim 1, in which the pharmaceutically active ingredient is morphine sulfate or morphine hydrochloride.

14. (Previously presented) A pharmaceutical dosage form according to claim 4, wherein the median t_{max} is in the range from about 2.5 to about 3.5 hours.

15. (Previously presented) A pharmaceutical dosage form according to claim 4, wherein the W_{50} is in a range from about 15 to about 35 hours.

16. (Previously presented) A pharmaceutical dosage form according to claim 4, wherein the W_{50} is in a range from about 20 to about 30 hours.

17. (Previously presented) A pharmaceutical dosage form according to claim 4, wherein the weight ratio of hydrophobic fusible material to hydrophilic organic polymeric wicking agent in said mixtures in the range from about 8:1 to about 16:1.

18. (Previously presented) A pharmaceutical dosage form according to claim 4, wherein the pharmaceutically active ingredient is morphine, a pharmaceutically acceptable salt thereof or mixture thereof.

19. (Previously presented) A pharmaceutical dosage form according to claim 4, wherein the pharmaceutically active ingredient is morphine sulfate or morphine hydrochloride.

20. (Previously presented) A pharmaceutical dosage form according to claim 5, wherein the pharmaceutically active ingredient is morphine, a pharmaceutically acceptable salt thereof or mixture thereof.

21. (Previously presented) A pharmaceutical dosage form according to claim 5, wherein the pharmaceutically active ingredient is morphine sulfate or morphine hydrochloride.

22. (Previously presented) A pharmaceutical dosage form according to claim 1, which is suitable for once a day dosing.

23. (Previously presented) A pharmaceutical dosage form according to claim 17, which is suitable for once a day dosing.

24. (Previously presented) A pharmaceutical dosage form according to claim 4, in the form of a tablet or capsule containing multiparticulates.

25. (Previously presented) A pharmaceutical dosage form according to claim 5, in the form of a tablet or capsule containing multiparticulates.